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Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Albumin (ALB) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

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3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Albumin (ALB) Reagent

3.2 **Classification Names**

Albumin immunological test system (21 CFR 866.5040)

4.0 **Predicate Device(s):**

Beckman Immunochemistry Systems ALB Albumin Reagent

5.0 **Description:**

The IMMAGE Immunochemistry System Albumin (ALB) Reagent, in conjunction with Beckman Calibrator 3, is intended for use in the quantitative determination of human albumin concentrations in human serum and cerebrospinal fluid (CSF) samples. The reagent kit contains one cartridge of reagent, evaporation caps and a lot specific bar code card. Calibrators and control materials are purchased separately.

6.0 Intended Use:

The IMAGE Immunochemistry System Albumin (ALB) reagent, in conjunction with Beckman Calibrator 3, is intended for use in the quantitative determination of human albumin concentrations in human serum and CSF samples by rate nephelometry. This assay is designed for use with the Beckman IMAGE Immunochemistry System.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMAGE System (ALB) Reagent	Assay method - rate nephelometry	Same as Beckman's Immunochemistry System Albumin ALB Reagent as run on the ARRAY [®] System
	Serum: Analytic Range 800 - 6000 mg/dL Extended Range 22.2 - 6000 mg/dL	
	CSF: Analytic Range 3.7 - 27.8 mg/dL	
	Sample and reagent ratios	
	Antibody	
	Shelf life of 24 months (stored at 2 -8°C)	
DIFFERENCES		
IMAGE System (ALB) Reagent	Reaction Temperature	IMAGE System ALB assays run at 37°C and the predicate runs at 26.7°C
	Antigen excess solution (AGXS)	IMAGE System ALB Reagent AGXS is prediluted and present in the reagent cartridge while the predicate requires off-line preparation of the solution

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Beckman Immunochemistry System ALB Albumin (on ARRAY) Reagent to the IMAGE System ALB Reagent.

Method Comparison Study Results
 IMAGE ALB Reagent vs.
 Beckman Albumin Reagent (ALB) on ARRAY

Analyte	Sample Type	Slope	Intercept	r	n	Predicate
IMAGE ALB	Serum	1.020	10.3	0.997	164	Beckman Albumin Reagent (ALB) on the ARRAY® Systems
IMAGE ALB	CSF	0.990	0.692	0.994	101	Beckman Albumin Reagent (ALB) on the ARRAY® Systems

Stability Study Results

Reagent	Product Claim
IMAGE ALB Reagent System	24 month shelf-life 14 day open container stability 14 day calibration stability

Precision Study Results
 IMAGE ALB Reagent

Material Serum	Mean (mg/dL)	SD (mg/dL)	%CV	N
Within Run Precision				
Level 1	2268	40.4	1.8	80
Level 2	3563	56.6	1.6	80
Level 3	4996	115.2	2.3	80
Total Precision				
Level 1	2268	55.4	2.4	80
Level 2	3563	68.5	1.9	80
Level 3	4996	121.2	2.4	80

Precision Study Results
 IMAGE ALB Reagent

Material CSF	Mean (mg/dL)	SD (mg/dL)	%CV	N
Within Run Precision				
Level 1	5.13	0.227	4.4	30
Level 2	12.5	0.53	4.2	30
Level 3	20.7	0.71	3.4	30
Total Precision				
Level 1	5.13	0.356	6.9	30
Level 2	12.5	0.58	4.6	30
Level 3	20.7	0.87	4.2	30

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.